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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,223	12/14/2001	R. Martin Emanuele	19720-0229 (42896/263913)	9686

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EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 11/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/017,223	Emanuele
Examiner	**Art Unit**
Richard Schnizer	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 27, 2002*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *36-41* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *36-41* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

A preliminary amendment was received and entered as Paper No. 5 on 2/27/02.

Claims 1-35 were canceled.

Claims 36-41 were added and are under consideration in this Office Action.

Claim Objections

Claim 38 is objected to because "polyoxyehtylene" is misspelled in line 7 of the claim.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 36-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the following U.S. Patents.

Instant claims rejected	Patent No.	Patented claims	Supporting specification passage
36-41	6,359,014	1, 2, 5, 6, 11, 16	Col. 14, lines 9-31.
36-41	RE37,285	4, 7, 11, 18	Col. 15, lines 20-45
36-41	5,691,387	4, 7, 11, 18	Col. 13, line 60 to col.14, line 14
36, 38, and 40	5,674,911	1	Col. 7, lines 9-13; col. 15, lines 11-17

Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are drawn to compositions for treating patients, or to methods for treating patients, wherein the compositions have physical characteristics falling within the ranges recited in the instant claims. It is noted that the instant claims are broadly drawn to methods of preventing cell damage wherein the only active method step is the administration of a composition to a patient. For this reason any patented claim that teaches administration of the recited composition to an animal, for whatever purpose, renders the instant claims obvious.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36-41 are indefinite because it is unclear what is intended by "substantially pure" and "non-pure". Claims 36, 37, 40, and 41 require a substantially pure composition that is less toxic than a corresponding non-pure composition, whereas claims 38, 39, and 42 require tat the purer composition must have less unsaturation. One of skill in the art cannot know the metes and bounds of the invention because the specification fails to define "substantially pure" or "non-pure", and does not provide any standard of comparison that would allow one to make these determinations. Consider the following hypothetical example. One has three compositions which are 30%, 50% and 90% pure, respectively, and toxicity of the compositions decreases with increasing purity. None of these compositions is 100% pure, so it is not clear if any of them is substantially pure, on the other hand it cannot be known if any or all are considered to be non-pure. If one does not know whether or not 50% pure is "substantially pure", then one cannot know whether the 50% pure composition is within the metes and bounds of the claims. The 50% pure composition is purer and less toxic than the 30% pure composition, but it is less pure and

more toxic than the 90% pure composition. Do the claims embrace the 50% pure composition or not?

The claims are also indefinite because the method steps are not concordant with the purpose set forth in the preamble. The methods require prevention of cell damage, but recite no step at which damage is prevented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 36, 38 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Emanuele et al (US Patent 5,674,911).

Emanuele teaches methods of treating infections in a human or animal by administering a POE/POP block copolymer comprising a POE portion between 1,200 and 15,00 D and wherein the POE portion represents about 1-50% of the weight of the copolymer. See claim 1. The

polydispersity of the copolymer may be 1.05. See column 15, lines 14-17. The copolymer is less toxic than corresponding prior art compositions, and is substantially free of unsaturated molecules. See column 6, lines 22-27. Because it is free of unsaturated molecules, the composition is considered to be substantially pure. The compound can be used to protect against damage to tissue cells by ameliorating infection.

Thus Emanuele anticipates the claims.

Claims 36, 38, and 40 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

These claims were rejected under 35 USC 102(e) over US Patent 5,674,911 to Emanuele et al for the reasons set forth above. The '911 patent lists two inventors not listed on the instant Application (Balasubramanian and Allaudeen) ad the instant application lists two inventors not listed on the '911 patent (Hunter and Culbreth). For this reason, it is not clear who has invented the claimed methods.

The Assignee is required to either name the first inventor of the conflicting subject matter or show the inventions were commonly owned at the time of Applicant's invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.

JAMES KETTER
PRIMARY EXAMINER